Phoenix®

Service Manual
Maintenance

CE 0086

C SA® US

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EP0243284; EP0403401; EP0428676; EP0418171; EP0465381; EP0467805; EP0501894; EP0658352; EP0813880; EP0900093; EP0330892; EP054702; EP0643301; EP0830155; EP0830156; EP0831945; EP0836486; EP0830153; EP0835493;

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JP2059115; JP3129326; JP3001235; JP2753242; JP3095223; JP3200594; JP1777042; JP2542728; JP2823513;

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Certifications

CE 0086	Indicates that the equipment conforms to Council Directive 93/42/EEC, of 14 June, 1993 relating to Medical Devices. Also indicates that the notified body which has approved the manufacture's quality system is the British Standards Institution (BSI).
C SA ® US	Indicates that the equipment conforms to the rules related to the Safety of Medical Electrical Equipment for U.S. and Canada. The "C" and "US" indicator adjacent to the CSA mark signifies that the product has been evaluated to the applicable ANSI/UL and CSA Standards, for use in the U.S. and Canada.

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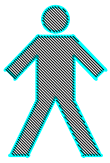
INTRODUCTION

IEC Symbols

	WARNING: Consult accompanying documents
	TYPE B APPLIED PART This apparatus provides an adequate degree of protection against electric shock, particularly regarding allowable LEAKAGE CURRENTS and reliability of the protective EARTH connection.
	OFF (Mains power disconnected)
	ON (Mains power connected)
	Alternating current
	Protective earth (ground)
	This symbol indicates that: - the equipment may not be disposed of together with other municipal waste; - the equipment was placed on the market after 13 August 2005.

	Keep dry
	Year of Manufacturing
	Name and address of the Manufacturer
	Serial Number

(from IEC 601.1)

User's Symbols

WARNING	Very important information related to the patient or operator safety, or given to avoid the machine breaking down. Read carefully before operating the machine.
NOTE	Important information related to the correct operation of the machine. Read carefully before operating the machine.

INTENDED USE

This Phoenix® Hemodialysis delivery system is intended to be used to provide high flux and low flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. This device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit.

WARNING

Fluid balance deviations, even if within the specified Phoenix accuracy, can exceed a level that can be tolerated by low-weight patients.

WARNING

The use of procedures not recommended by the manufacturer may result in patient injury or death. The Manufacturer does not assume responsibility for patient safety if the procedures described in this manual are not followed carefully and if staff who perform the procedures have not been appropriately trained and are not qualified.

WARNING

It is responsibility of the physician to ensure that the appropriate dialyzer and Cartridge Blood Set is selected for the weight of the patient being treated.

WARNING

This manual contains a number of references to accessories and disposables for use with the Phoenix machine. The Phoenix machine has been tested and validated for use with the accessories and disposables listed in this manual. The Manufacturer has not validated the use of accessories or disposables other than those specified in this manual. The Manufacturer does not assume responsibility or liability for use of accessories or disposable other than those specified in this manual. It is the responsibility of the user to validate that other accessories or disposables provide safe and effective performance.

SPARE PARTS

Note

The Manufacturer will maintain spare parts availability for ten years after the end of production of PHOENIX. At the end of that time the involved product is considered obsolete and therefore it must be disposed of according to local applicable regulations. The final user will be informed that spare parts are no longer available through the technical service or the sales representative.
For additional information contact your local technical service representative.

WARNINGS

WARNING

Do not assemble, install or use the machine before having read the Operator and Service manuals.

WARNING

This operation must be carried out by authorized personnel; if not, the Manufacturer cannot accept any responsibility for damage which may occur, and such damage is not covered by the warranty.

WARNING

Check the continuity and the reliability of the ground connection.

WARNING

Verify the quality of the protective earth ground at installation.

WARNING

Do not perform any technical intervention on the machine from the dialysis preparation phase until patient disconnection. Before performing any technical intervention on the machine, are sure that it has been properly disinfected

WARNING

Do not use this machine near flammable gas or flammable anaesthetic mixtures with air, with oxygen or with nitrous oxide.

WARNING

Storage under 0°C is only possible if the hydraulic circuit has been drained (see Maintenance section of this Manual)

WARNING

This equipment conforms to IEC 60601-1-2 standard on Electromagnetic Compatibility; thus it has an adequate degree of protection against electromagnetic disturbances.
However, to prevent any problem it is recommended not to use cellular phones (hand-held) in the dialysis room or - at least - to keep a minimum distance of 10 m from the equipment. Refer to local standards and guidelines.

WARNING

Possible hazards may arise from other equipment (different from the accessories listed in the Operator Manual) being connected to the hemodialysis machine, which may cause the maximum leakage current to be exceeded.

WARNING

The correct installation of a MEDICAL ELECTRICAL SYSTEM requires that each SYSTEM component be individually connected to the main power.
It is strongly recommended: NOT TO USE MULTIPLE PORTABLE SOCKET-OUTLETS.
However, if using multiple portable socket-outlets, they must comply with the IEC 60601-1-1 Standard and must NOT BE PLACED ON THE FLOOR.

WARNING

Wait at least 5 seconds between power off and power on cycles.

WARNING

Before moving the machine, check that the brake is released and remove infusion bags or hanging objects from the IV pole.

WARNING

It is recommended to use concentrates which conform to the requirements of the local standards or of the AAMI RD61 "Concentrates for hemodialysis" standard or of the European Pharmaceutical standards.
The control of alarm thresholds and dialysate conductivity precision is of major medical importance in ensuring a safe dialysis treatment.

WARNING

It is the responsibility of the user to determine the correspondence between the dialysate conductivity, displayed by the machine, and the dialysate solute content, verified by clinical laboratory results, for each dialysate concentrate used for dialysis treatment.
This can be done by taking dialysate samples at different conductivity values (e.g. 13,14,15 mS/cm) and sending them to a laboratory for analysis.

WARNING

Carefully read the BiCart® Instructions for Use before using the device. BiCart® may only be used by staff, who are specially trained for hemodialysis treatments, using the Operator Manual (see BiCart® paragraph).

WARNING

Only in the event of the "! CONCENTRATE TYPE ERROR: A PUMP or B PUMP or A&B PUMPS" alarm is when it possible to perform the Autocalibration of PA or PB pump in dialysis (see Maintenance Section) when the operator accesses the appropriate page by pressing the MACHINE Tab.

WARNING

In the case of Autocalibration of the Acetate or Bicarbonate pump, the user must verify that the concentrate at the machine concentrate inlet is correct and confirm this by pressing the Confirm button on the main keyboard.
The process will only proceed after this confirmation.
The use of incorrect concentrates can lead to an incorrect dialysate conductivity, not detectable by the Protective System.

WARNING

If a bicarbonate dialysis was performed, do not turn off the machine with bicarbonate dialysate fluid inside.
An acetic acid rinse must be performed at least twice a week to remove the calcium and residues which may be deposited in the system during dialysis treatments.

WARNING

The use of the Cartridge Blood Tubing's Set designed for the machine is recommended to guarantee safe and proper functioning of the system.

WARNING

Never insert fingers in the automatic clamp.
When the cover of the blood pump is open, verify that the pump is off.

WARNING

The Heparin Syringe diameters have been taken from samples from many countries and are correct at the time of going to press. However, the manufacturer cannot be held responsible for changes in syringe dimensions that may occur. The user should periodically check the correlation between the stated and the actual diameters.

WARNING

For the BPM installation, carefully follow the instructions supplied with the BPM kit.

WARNING

The BPM must only be used for adult patients with a body weight greater than 15 Kg and using a BPM cuff of the appropriate size.

Avoid squeezing or kinking of pressure tubes.

The BPM should be tested at least once every 4000 hours, or any time irregular performance is suspected or observed.

Insulating material protects the BPM "Applied Part" (Type BF) against the effects of a defibrillator discharge.

If the cuff or the pneumatic connections gets wet, wipe immediately to prevent moisture entering the machine.

WARNING

In order to fully comply with the indications of the European Medical Device Directive 93/42, the user is notified that the information originating from the BPM cannot be used alone as a unique source of information to induce any therapeutical or pharmacological actions.

WARNING

To prevent damaging the machine, do not leave disinfectant solution in the machine during the ADR CHEMICAL DISINFECTION procedure for periods over the following limits:
4 hrs for: Amuchina™, Instrunet HD™ and Sodium Hypochlorite at Disinfectant strength (1:25 dilution);
24 hrs for: Dialox™, Acetoper™, Peresal™, Actril® and Renalin®;
48 hrs for: formaldehyde solution and Steridial™;
One week for: Sodium Hypochlorite at Bacteriostatic strength (1:750 dilution).

WARNING

When the DiaClear ultrafilter is installed, the CHEMICAL DISINFECTION must only be performed with an approved disinfectant in order not to damage the DiaClear ultrafilter.

WARNING

For the disinfection of the ultrafilter it is mandatory to use only the chemical agents recommended in the DiaClear Instructions for Use, compatible with the equipment. The maximum concentration allowed for the disinfectant used is:
6% Sodium Hypochlorite
4% Peracetic acid
40% Formaldehyde
100% Instrunet
100% Steridial

Refer to the DiaClear Instructions for Use.

Some solvents or other chemical products used for cleaning can damage the DiaClear ultrafilter: Refer to the DiaClear Instructions for Use for the list of non validated products.

WARNING

The user must take precautions against the hazard of cross-infection between patients by disinfecting the accessible surfaces of the equipment.

WARNING

Do not use chemicals which might damage the plastic parts of the machine .
Avoid chemicals containing benzene, toluene, xylene, acetone or similar solvents.

WARNING

Any fluid spilled on the machine must immediately be cleaned to prevent it from getting into the machine.

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WARRANTY I

A. Appendix A: Guidelines and Manufacturer's Declaration - Electromagnetic Emissions and Immunity ***..... A-1***

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